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09/615,643	07/13/2000	Thomas L. Meredith	N-6089RSM	4680

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WADDEY & PATTERSON  
414 UNION STREET, SUITE 2020  
BANK OF AMERICA PLAZA  
NASHVILLE, TN 37219

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

# Office Action Summary

Application No.

09/615,643

Applicant(s)

MEREDITH, THOMAS L.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 19,21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/15/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### *Drawings*

The drawings were received on 4/15/03. These drawings are acceptable for examination, but Formal drawings will be required upon allowance.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18,32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although Applicant mentions that the bone particles and the bone screw are hydrated on pages 12 and 14 respectively, there is no mention that the composite is a solid structure or that it maintains this solid structure after hydration. Additionally, the claims do not recite how hydration is accomplished, since claims 1 and 32 only mention the use of a binder, thus the claims imply that the binder possibly hydrates the material since the binder is in fluid form when added to the bone material and then allowed to cure or solidify. However, the implied limitation "the binder resulting in hydration" is not supported in the specification.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (4645503). Lin et al. disclose that bone tissue can be used in forming a bone composite, col. 3, lines 16-25. Since Lin discloses the bone is in the form of chips, it is inherently ground bone tissue. Lin additionally discloses the binder with the implant material are shaped or "molded" and cured by heating in the bone site, thus forming a solid structure, col. 6, lines 42-51. Lin also discloses that the material can be solid or in block form, col. 6, lines 10,11. It is inherent that the bone tissue is osteoinductive since the tissue is bone, the same as what Applicant claims.

Claims 1-3,8-12,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowd et al. (5507813). Dowd et al. disclose the use of bone particles with binders to form a bone composite, col. 1, lines 47-50. Dowd also discloses the particles are obtained by milling or "grinding" into a size within the range of 125 to 850 microns, col. 2, lines 51-54. The bone used can be cortical and demineralized, col. 3, lines 19,20, 26-29. Dowd additionally discloses the bone particles are mixed with adhesives, which inherently would form an organic matrix, col. 3, lines 66,67. The composite material is soaked with a binder and then molded, col. 4, lines 58-67. Dowd discloses a pressure within 14.7 to 30,000 psi to mold the composite, col. 5, lines 19-24. The material cures after it is implanted and hydrated. Binders can be applied before or after shaping or "molding," col. 4, lines 2-4. The bone composite can be a pin or screw, col. 7, lines

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23,24. Dowd discloses the bone composite maintains its solid structure after hydration in the body, col. 6, lines 54,55.

Claims 1-3,10,12,14,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyle (5061286). Lyle discloses a method of forming a bone composite by grinding bone tissue and demineralizing the bone, col. 3, lines 9-12. Lyle also discloses the particles can contain an organic matrix in the form of a collagen lattice, col. 3, lines 48-53,66. The bone used can be cortical, col. 3, lines 5-8. Lyle additionally discloses the bone particles are mixed with the binder cyanoacrylate and sprayed on, col. 4, lines 15-23. Binders can be applied before molding, col. 5, lines 48-58. The bone and binder can also be combined as a powder mixture which is cured by heating and then applied as a coating, such that it can be applied on the prosthesis in layers, col. 6, lines 3-22. The composite forms a solid structure by being molded onto a prosthesis and is self-supporting which inherently means it is "solid" enough to provide rigidity and possess weight bearing properties.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Glimcher et al. (5565502). Glimcher et al. disclose a method of using bone tissue by grinding the bone into ground tissue of a size between 125-850 microns, col. 7, lines 16-19. Glimcher also discloses a binder, such as a cyanoacrylate can be added with the bone particles, col. 11, lines 57-60. Glimcher also teaches the bone composite can be applied on the surface of prostheses (col. 11, lines 61-64, col. 12, lines 35-39) which inherently implies the bone composite is molded and pressure is applied by the device delivering or applying the material. The bone composite is molded to the shape of the

prostheses and inherently the composite will solidify after application. Glimcher additionally discloses the bone composite material maintains a "solid structure" or acts as a structural support after hydration by the adhesive (as best understood according to the Applicants claim), col. 11, lines 63-66.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813. Dowd et al. is explained supra. However, Dowd et al. do not disclose the percentage of cortical bone in the bone tissue. It would have been an obvious matter of design choice to a person of ordinary skill in the art to use greater than 50% or up to 95% cortical bone tissue as the specific percentage used in the Dowd et al. composite because Applicant has not disclosed that any specific percent provides an advantage over another, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the percent of cortical bone as taught by Dowd et al. or the claimed greater than 50% or up to greater than 95% cortical bone because all percentages of cortical bone particles will still form a solid bone composite.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle '286 in view of Bonutti (6132472). Lyle is explained supra. Lyle does disclose adding attachment agents to the bone particles, col. 4, lines 4,5. However, Lyle does not

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disclose the addition of fibrin in the bone composite. Bonutti teaches that fibrin can be added to bone material used as an implant, col. 3, lines 61-67. It would have been obvious to a person of ordinary skill in the art to use fibrin in the bone composite as taught by Bonutti in the Lyle composite because fibrin is tacky and is capable of holding particles together.

Claims 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle '286. Lyle is explained supra. However, Lyle does not disclose the type of cyanoacrylate used. It would have been an obvious matter of design choice to a person of ordinary skill in the art to use ester chain or long chain cyanoacrylates as the specific cyanoacrylate binder used in the Lyle composite because Applicant has not disclosed that any specific cyanoacrylate provides an advantage over another, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the cyanoacrylate taught by Lyle or the claimed ester or long chain cyanoacrylate binders because both types hold together the bone particles.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813. in view of Bonutti (6132472). Dowd et al. '813. is explained supra. However, Dowd et al. do not disclose using a die to shape and mold the bone particles. Bonutti teaches that a die is used to form the bone tissue into the desired shape, col. 11, lines 13-36. It would have been obvious to a person of ordinary skill in the art to use a die to mold the bone composite as taught by Bonutti in the Dowd et al. composite because this would produce a composite having a preset or known dimension which is desirable.

### ***Response to Arguments***

Applicant's arguments filed 4/15/03 have been fully considered but they are not persuasive. In response to applicant's argument that Lin fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., osteoinductive **particles**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If any additional bioactive material is added in Applicant's bone composite that makes it osteoinductive then it should be claimed. If this is not the case, then since the same material (bone) is used by Lin as what Applicant is claiming, Lin anticipates claim 1. With respect to the Dowd reference it is noted that Dowd mentions the composite maintains its shape or solid structure even after hydration in the body. Regarding the remarks that the Applicant defines "solid structure" as providing rigidity and weight bearing properties is unsupported because no definition was found in the disclosure to define this terminology. With respect to the Lyle patent, the fact that it is a coating does not exclude the patent from anticipating the claims. Since Lyle discloses the composite including the binder and bone form a "self-supporting" mass it is fully capable of being characterized as a solid structure. Applicant's claims recite the composite (everything that it is made from) forms the solid structure and this is the same as what Lyle discloses form the composite. Regarding the Glimcher patent, the fact that it can be used as a coating is irrelevant to the issue of patentability of the claim language.



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Glimcher clearly discloses that the composite with an adhesive that inherently solidifies into a solid structure provides structural support and can be in block form or a solid.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-


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5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino  
June 25, 2003  
TC 3700, AU 3738



Paul Prebilic  
Primary Examiner